Response to Office Action dated April 14, 2004

Remarks:

Amendments to the Specification and Claims

The Title has been replaced.

In the specification, the paragraph beginning at page 128, line 1, has been replaced to correct typographical errors. Additionally, the paragraph beginning at page 143, line 9, has been replaced to correct typographical errors.

Reconsideration of the application in view of the above amendments and following remarks is requested. Claims 1-16, 22, and 24 are now in the case. Claims 3,4,5,7,8,9,10 have been amended to capture certain embodiments of the invention.

Response to Claim Rejections under 35 U.S.C. § 112 and A) 35 U.S.C. § 112:

Claims 1-16, 22, and 24 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. The Office Action stated that the specification appears to provide a credible use for the polynucleotides of SEQ ID NO:1, and states that this use may extend to the polynucleotides of SEQ ID NOs: 18 and 20 and to the fragments set forth in claim 2. However, the Office Action alleged that this use cannot be "confirmed" with the information in the specification. In addition, Claims 1-5 were rejected under 35 U.S.C. § 102(b) as being anticipated by Genbank Accession Number AL358412.8, having a publication date of October 29, 2000. The Office asserts that the instant application does not receive benefit of priority to either of its 60/253,561 provisional application filed November 28, 2000, or of its 60/267,211 provisional application filed February 7, 2001, because there is no disclosed use of the polynucleotides or polypeptides of the instant invention in the provisional applications.

Applicants respectfully disagree with the Office's assertions. The Office appears to have not fully appreciated that the specification teaches, and fully enables, <u>multiple</u> uses for the polynucleotides of the instant application. For example, the specification teaches that the polynucleotides of the instant invention are useful for detecting genetic variations in its sequence, such as serving as a marker for and detecting an underlying disease. See, for example, page77, line 29 to page 78, line 7 of the instant specification. This use is also taught on page 53, lines 8-21 of the Provisional Application 60/253,561, and on page 56, lines 14-27 of the Provisional Application 60/267,211. See also page 79, line 30 to page 80, line 2 of the instant specification. This use is also taught on page 55,

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lines 13-16 of the Provisional Application 60/253,561, and on page 58, lines 20-23 of the Provisional Application 60/267,211.

The specification also teaches that the polynucleotides of the invention can be used to serve as a marker for detecting translocations, aneuploidy, rearrangements, LOH other chromosomal abnormalities involving this chromosomal region that are present in cancers in this region. See page 105, lines 1-3 of the instant specification, for example. This use is also taught, for example, on page 79, lines 1-4 of the Provisional Application 60/253,561 and on page 83, line 16-19 of the Provisional Application 60/267,211.

Genetic variations of the polynucleotides of the present invention can readily be determined by either PCR from a DNA sample or by hybridization. There are many teachings in the present specification of isolating the gene by PCR (See, for example. Examples 2, 3, 4, pages 114-121 of the present specification; pages 88-93 of the Provisional Application 60/253,561; pages 93-99 of Provisional Application 60/267,211. Methods of hybridization are taught in the specification at, for example, pages 27-28 of the instant specification; pages 22-23 of the Provisional Application 60/253,561; pages 25-26 of the Provisional Application 60/267,211.

Not only can the polynucleotides be used to detect a gene's up- or downregulation and genetic variations, as one of ordinary skill in the art readily knows, polynucleotides are useful in production of the polypeptides of the present invention. As a cytokine receptor, the polypeptides are useful to treating infections. See for example, page 57, line 29 to page 58, line 1, teaching that agonists and anti-zcytor19 antibodies are useful to treat infections involving immunosuppression, including viral infections. This is also taught, for example, on page 52, lines 21-31 of Provisional Application 60/253,561, and on page 55, line 27 to page 56, line 6 of the Provisional Application 60/267,211. Additionally, see page 101, line 23 to page 102, line 2, teaching that antagonist or agonists, to the receptor would be important in boosting immunity to infectious diseases. This is also taught, for example, on page 75, line 24 to page 76, line 3 of the Provisional Application 60/253,561, and on page 80, lines 8-18 of Provisional Application 60/267,211. In addition to treating infections the polypeptides of the present invention are useful in tumor suppression. See, for example, page 79, line 21, to page 80, line 2, teaching the use of soluble receptor to detect ligand-expressing solid tumors. This is also taught, for example, on page 55, lines 4-16 of the Provisional Application 60/253,561, and on page 58, lines 11-23 of Provisional Application 60/267,211.

Methods of using the polynucletotides of the present invention to produce the polypeptides, including soluble receptor, and thus antibodies, of the present invention are discussed in the specification at pages 45-53 of the instant specification; pages 40-46 of

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the Provisional Application 60/253,561; pages 43-51 of Provisional Application 60/267,211.

In summary, the polynucleotides of the present invention are useful not only in detecting genetic variations of the Zcyotr19 gene, but also for producing the zcytor19 polypeptides and the soluble receptor, and thus anti-zcytor19 antibodies, of the present invention.

It seems that the Office understands the polynucleotides of the present invention to have only one credible use: to carry out *in situ* hybridization as per the method taught in Example 14 of the instant specification. In addition, the Office Action states that the chromosomal mapping of the polynucleotides of the present invention does not provide a specific utility, and that the encoding nucleic acid of the present invention does not have a specific utility as a member of the class II cytokine receptor family. Furthermore, it appears that the Office understands that the method of Example 14 could only be carried out with the plasmid specified in this particular example. The instant specification teaches that 0.7kb from the 3' UTR of the polynucleotide were used to detect upregulation of zcytor19 in carcinoma samples. See Example 14, page 141, lines 24-25. One of ordinary skill in the art will know that *any portion* of the cDNA as shown in SEQ ID NO:1, SEQ ID NO:18, or SEQ ID NO:20 can be used to detect upregulation of the gene. As such, said person of ordinary skill in the art will know that probing carcinoma samples with a portion of said cDNA sequence(s) is useful for such purposes. Additional probes and oligos are taught throughout the specification as discussed above.

Applicants have shown that the polynucleotides of the present invention are useful and are fully enabled from the date of the first Provisional application. As such, the reference cited by the Office, GenBank Accession No. AL58412.8 does not stand as a 35 U.S.C § 102(b) barrier to the claims of the present patent application. In addition, the GenBank reference discloses only the genomic sequence, with nothing to indicate to one of ordinary skill in the art the polynucleotide sequence of the corresponding cDNA: no open reading frame or intron –exon junctions.

On the basis of the above amendments and remarks, Applicants believe that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. If for any reason the Examiner feels that a telephone

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conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6752.

Respectfully Submitted,

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Enclosures:

Petition and Fee for Extension of Time (in duplicate) Amendment Fee Transmittal (in duplicate) Postcard